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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,812

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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,812	Applicant(s) JAYASHEELA ET AL.	
	Examiner Jennifer Dunston	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009 and 15 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,11,12,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,11,12,22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/5/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This action is in response to the amendment, filed 5/15/2009. Receipt is also acknowledged of an amendment filed 1/16/2009, in which claims 1-6, 9-10 and 13-21 were canceled, and claims 7, 8, 11 and 22 were amended. Claims 7, 8, 11, 12, 22 and 23 are pending.

Applicant's arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn. **This action is FINAL.**

Election/Restrictions

Applicant elected Group IV with traverse in the reply filed on 7/11/2008. Claims 7, 8, 11, 12, 22 and 23 are under consideration.

Information Disclosure Statement

Receipt of an information disclosure statement, filed on 8/5/2009, is acknowledged. The signed and initialed PTO 1449 has been mailed with this action.

Specification

The disclosure is objected to because of the following informalities:

1. Page 9 contains the heading "BRIEF DESCRIPTION OF THE DRAWINGS"; however, the application does not contain any drawings.
2. The citation at page 16, line 12 is incomplete. The "xxxx" should be replaced with the page number.

Appropriate correction is required.

The use of the trademark PROVENTIL (paragraph [0133]) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Response to Arguments - Specification

Applicant's arguments filed 1/16/2009 have been fully considered but they are not persuasive.

The response asserts that the specification was amended to correct the abovementioned informalities; however, the amendment filed 1/16/2009 was non-compliant and was not entered. Applicant was required to resubmit the entire section of the reply that was noted as being non-compliant in the letter mailed 4/23/2009. However, in the amendment filed 5/15/2009, only paragraph [0078] was amended. Thus, all informalities have not been corrected by amendment, and the objection is maintained.

Claim Objections

Claim 7 is objected to because of the following informalities: the preamble recites a "method of reducing a bacterial population: in a subject in need of said treatment." In the reply filed 1/16/2009, the preamble was amended to refer to "reducing a bacterial population" rather

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than "treating a bacterial population." Thus, "said treatment" no longer explicitly refers back to the preamble. It would be remedial to replace "in need of said treatment" with "in need of treatment." Appropriate correction is required.

Response to Arguments – Claim Objections

The objection of claims 7, 8, 11, 12, 22 and 23 has been withdrawn in view of Applicant's amendment to the claims in the reply filed 1/16/2009.

Response to Arguments - 35 USC § 112

The rejection of claims 7 and 8 under 35 U.S.C. 112, first paragraph, has been withdrawn in view of Applicant's amendment to the claims in the reply filed 1/16/2009.

Response to Arguments - 35 USC § 102

The rejection of claims 7, 8, 11, 12, 22 and 23 under 35 U.S.C. 102(b) as being anticipated by Bläsi (WO 02/34892 A1) has been withdrawn in view of Applicant's amendment to the claims in the reply filed 1/16/2009. Bläsi does not teach a method of administering an isolated phage tail.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 8, 11, 12, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinomiya et al (Journal of Virology, Vol. 32, No. 3, pages 958-967, December 1979; see the entire reference) in view of Haas et al (The Journal of Infectious Diseases, Vol. 129, No. 4, pages 470-472, April 1974; see the entire reference). This is a new rejection, necessitated by the amendment filed 1/16/2009.

Shinomiya et al teach an isolated phage tail of bacteriophage PS17, which has bactericidal activity that inhibits growth of certain strains of *Pseudomonas aeruginosa* PML14 when administered to the cells (e.g., page 958, paragraph bridging columns; pages 961 and 963, Purification of the tail of PS17; pages 964-965, Mode of action of the tail; Table 1; Figure 8). Shinomiya et al suggest that the tail of PS17 might kill cells by a method similar to R-type pyocins (e.g., page 965, left column, full paragraph).

Shinomiya et al do not teach the administration of the phage tail to a subject in need of treatment, where the subject is a mammal, where the subject is a food, work, display or

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companion animal, or where the method comprises administering a second therapeutic antimicrobial agent.

Haas et al teach that pyocin protects against lethal *P. aeruginosa* infections in mice (e.g., Abstract). Haas et al teach intraperitoneal (ip) injection of pyocin at different times before or after ip challenge with *P. aeruginosa* (e.g., Material and Methods). Haas et al teach that pyocin has been shown to be therapeutically effective against experimental *P. aeruginosa* infection in mice, and report that ip injection of pyocin had a marked protective effect against subsequent ip inoculation of viable organisms (e.g., page 470, left column, 1st paragraph; page 470, right column, 3rd full paragraph; Table 1). Haas et al teach that *in vitro* susceptibility to pyocin reliably correlates with *in vivo* protective effect (e.g., page 471).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the phage tail of bacteriophage PS17 of Shinomiya et al to mice infected with *P. aeruginosa* as taught by Haas et al. Shinomiya et al teach it is within the ordinary skill in the art to use an *in vitro* test to determine the ability of the phage tail to kill strains of *P. aeruginosa* (e.g., Table 1). Further, Shinomiya et al teach that the phage tail might kill cells in a manner similar to R-type pyocins, and Haas et al teach the administration of pyocins to treat *P. aeruginosa* infection. It would have been obvious to one of ordinary skill in the art to administer the phage tail of Shinomiya et al either alone or in combination with the pyocin of Haas et al, because both compositions have bactericidal activity towards *P. aeruginosa*.

One would have been motivated to make such a modification in order to receive the expected benefit of treating *P. aeruginosa* infection as taught by Haas et al. Based upon the teachings of the cited references (e.g., the reliable correlation of *in vitro* and *in vivo* activity

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taught by Haas et al), the high skill of one of ordinary skill in the art, and absent any evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston
Examiner
Art Unit 1636

/JD/

/ Christopher S. F. Low /
Supervisory Patent Examiner, Art Unit 1636